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09/781,427	02/13/2001	Joseph P. Steiner	22789XA-T	3405	
75	90 12/19/2002				
Gary M. Nath NATH & ASSOCIATES PLLC 6th FLOOR 1030 15th Street, N. W. Washington, DC 20005		EXAMINER			
			COOK, RI	COOK, REBECCA	
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			1614		
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Paper No. 14

Application Number: 09/781,427 Filing Date: February 13, 2001 Appellant(s): STEINER ET AL.

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DEC 1 9 2002

GROUP 2900

Sean Passino For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed October 15, 2002.

(1) Real Party in Interest

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A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 11-14 and 17 stand or fall together for each ground of rejection because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

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The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

CA128:43577 Mcelwee, K.J. et al 1997

CA122 :230322 | Iwabuchi, T. et al 1995

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Rejection under 35 U.S.C. 112, first paragraph

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some of the compounds, does not reasonably provide enablement for rapamycin. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. To the extent that intended use of a composition is patentable CA 122:230322 (abstract, lines 8-9) discloses that rapamycin does not initiate hair growth. Appellants argue that because the claims are presumed enabled and the evidence of record provide no basis to infer that any claimed compound would not treat alopecia, nothing of record casts doubt on the enablement of rapamycin. This is not persuasive. It would be obvious that since CA122:230322 discloses that rapamycin does not initiate anagen hair growth that rapamycin would not be useful in a composition to treat alopecia or promote hair growth.

Rejection under 35 U.S.C. 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over CA 128:43577.

CA 128:43577 (abstract, lines 15-23) discloses that FK506, a compound meeting the description of the compound of claims 11-14, promotes hair growth and can be used to treat alopecia. The instant claims differ over the reference in reciting a composition combined with a second agent that promotes hair growth. However, in the absence of a showing of unexpected results it would be obvious to one of ordinary skill in the art to combine two compounds, each or which promote hair growth, in a composition. One would be motivated by the desire to increase the amount of hair growth.

Appellants argue that there is no motivation in the prior art to combine two compounds. This is not persuasive. The idea of combining two agents, each of which is known to be useful to promote hair growth, flows from knowing that each alone has the same use. In re Kerkoven 205 USPQ 1069.

Rejection under the judicially created doctrine of obviousness-type double patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

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USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 11 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-6 of copending Application No. 09/784,174. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claim is obvious when the compound of 09/784,174 is an N-linked ketone.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Appellants argue that that overlap cannot support a double patenting rejection. This is not persuasive. The compound of claim 11 and the compound of claims 5-6 of 09/784,174 would be the same compound when they are an N-linked ketone and in the absence of a terminal disclaimer to the instant application there would be an extension of monopoly on the claims of the later issuing application.

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(11) Response to Argument

All issues raised by appellant were fully responded to under the Grounds of Rejection portion above.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Rebecca Cook
Primary Examiner
Art Unit 1614

RC December 17, 2002

Conferees

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